JUL 19 2006

K061909

510(k) Summary

Submitter:	OmniGuide Inc. One Kendall Square, Building 100 3rd Floor Cambridge, MA 02139
Contact Person:	Irina Kulinets
Telephone:	617-551-8404
Fax:	617-551-8445
Proprietary Name:	Highland Beam Delivery System
Common Name:	CO_2 Laser Powered Surgical Instrument
Classification:	878.4810
Product Code:	GEX
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.

Substantial Equivalence Claimed To:

K992472 Clinicon SureGuide CO_2 Laser Beam Delivery System.
K014048 Clinicon Universal WaveGuide Handpiece and Fiber Tips
K924664 Surgilase Fiberlase CO_2 Laserwave Guide
K921671 Surgilase Fiberlase V CO_2 Laser Waveguide
K896478 Luxar LX-20 Minilase CO_2 Surgical Laser
K031440 Cynosure Smart CO_2 Medical Laser System
K963189 ERBE APC 300 Argon Plasma Coagulator

K050541 OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery System

Description:

The Highland Beam Delivery System is the CO_2 laser beam delivery system that can be retrofitted to Luxar LX-20 or Lumenis NovaPulse CO_2 laser. It consists of a laser adapter with a fiber cable and optical fiber handpiece that propagate CO_2 laser beam, cooling devices for fiber cable and movable cart that houses all system components.
The optical fiber handpiece consists of optical fiber integrated with a handpiece. It is supplied sterile and is intended for single procedure use. The laser adapter and fiber cable are re-usable devices that transmit CO_2 laser radiation from the laser to the fiber assembly.

Intended Use:

The Highland Beam Delivery System is intended for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues
The indications for use for which the delivery system is used are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.

Summary of Technological Characteristics:

The device consists of the optical fiber handpiece, the laser adapter with fiber cable for connecting the fiber assembly to the laser and the unit regulating the amount of cooling gas entering the fiber core and providing the liquid coolant for fiber cable cooling. The system components are mounted on the movable cart. The main functional component of the optical fiber handpiece and fiber cable is a photonic bandgap optical fiber. Its hollow core contains highly reflective lining and it thereby guides CO_2 laser energy. The optical fiber handpiece and fiber cable connected together are about 2.1 m long and transmit at the CO_2 laser emission wavelength of 10.6 μm. To maintain high transmission power capacity and reliability of multiple use fiber cable, it is actively cooled by recirculated liquid coolant supplied by recirculating chiller.

Performance Data:

Non-clinical Performance Data: The Highland Beam Delivery System performance characteristics have been evaluated through bench testing and analysis of laser power output and beam quality. This type of testing complies with the respective section of the FDA Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995) and IEC 60601-1 and 2 and is similar to the predicate device tests. The performance of the Highland Beam Delivery System and related parameters of predicate devices (as specified in comparison table) are comparable. The materials of optical fiber handpiece have passed biocompatibility testing as performed by an independent laboratory in accordance with ISO 10993-1:2003 Standards.
Clinical Performance Data: Formal clinical trials were not deemed necessary as the device has the same core technology and intended use as predicate devices. The market surveillance of previously cleared OmniGuide device (K050541) that is using the same core fiber technology and has the same intended use and tissue interaction mechanism indicated that the devices performed as intended.

Conclusions Drawn from Tests and Analysis:

The current version of the device does not present any differences in the delivery, quality and / or control of laser beam and does not change the interaction between the laser beam and human tissue. The only differences presented in this submission in comparison to OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery System previously cleared via K050541 are improvements in the device reliability and convenience for use, introduced by utilization of actively cooled fiber cable and better controlled cooling methods for fiber.

The intended use and major performance parameters (energy transmission levels and beam quality) of the Highland Beam Delivery System are similar or equivalent to same characteristics of above mentioned legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

OmniGuide, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K061909
Trade/Device Name: Highland Beam Delivery System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 3, 2006
Received: July 6, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

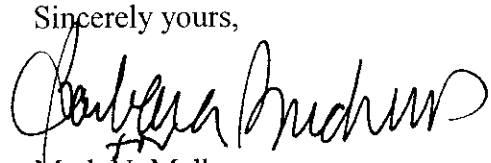
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061909

Device Name: Highland Beam Delivery System

Indications for Use:

The OmniGuide's Highland Beam Delivery System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral / maxillofacial surgery, dentistry, dermatology, endoscopic surgical procedures related to gynecology, otorhinolaryngology, neurosurgery, gastroenterology, and pulmonary surgery for surgical and aesthetic applications. The indications for use for which the device is used are also dependant upon the cleared indications for use of the laser system and the laser system accessories to which it is attached.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061909